

70144-2

04/20/2015

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 20, 2015

Abigal T.D. Wacek
Regulatory Consultant
Technology Sciences Group Inc.
1150 18th Street, Suite 1000
Washington, DC 20036

Subject: Notification per PRN 98-10 – Add a description of the action here
Product Name: Opti-Cide 3 Wipes
EPA Registration Number: 70144-2
Application Date: March 17, 2015
Decision Number: 502434

Dear Ms. Wacek:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions, you may contact Terria Northern at 703-347-0265 or via email at northern.terriat@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Hebert", is written over a horizontal line.

for

John Hebert, Branch Chief
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Opti-Cide® 3 Wipes

[ABNs:] {Opti-Cide® 3 Surface Wipes} {Opti-Cide® 3 V Surface Wipes} {Opti-Cide® Surface Wipes} {Opti-Cide® 1 Surface Wipes} {Opti-Cide® 2 Surface Wipes}

[Insert marketing statements, as appropriate, from *Marketing Copy* and/or *Directions for Use*]

Active Ingredients:

n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
dimethyl benzyl ammonium chloride	0.154%
n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl	
ammonium chloride	0.154%
Isopropanol	21.000%
Other Ingredients	78.692%
Total	100.000%

Keep Out of Reach of Children
CAUTION

See back [side] panel for additional Precautionary Statements.

EPA Reg. No. 70144-2 EPA Est. 1130-IL-4

Net Contents: _____ wipes
Net Weight: _____ oz. (_____ g)

Product Order Number: _____



Made in the U.S.A.

NOTIFICATION

70144-2

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/20/2015

[Back/Side Panel(s)]

[Marketing Copy]

[Choose as appropriate]

Antibacterial
Antimicrobial
Bactericidal
Broad Spectrum
Cleaner {Cleans}
Decontaminant
Decontaminates
Disinfectant {Disinfects} {Soft} {Hard} Surfaces in {2} {3} {5} (as appropriate) minutes
Disinfects
Disinfectant
Cleaner
Deodorizer

Equipment
{Use on} Pet Care Surfaces
Fragrance free
Fungicidal
Germicidal
General
Sanitizer
Sanitize{s}
Hospital
Healthcare
Housekeeping
In-home {Use}
Kills Tuberculosis, BCG {var bovis.}, {TB}, {Gram-positive and Gram-negative} Bacteria, {Enveloped & Non-Enveloped} Viruses*, Fungi in [2] [3] [5] minutes
Kills Bacteria, Viruses*, Fungus on pre-cleaned, hard, non-porous surfaces such as {select from use directions}
Spot Cleans
Kills {names taken from list of approved microorganisms}
Kills {99.9% of bacteria} {or} {germs}
{Pre-cleaning} Instrument {device} Soak
Kills Pandemic 2009 H1N1 Influenza A Virus* {formerly called "swine flu"}
{Medical}/{Surgical}/{Dental}, {Veterinary} Equipment Disinfectant Cleaner and Decontaminant
{Surface} Disinfectant/Decontamination Cleaner
{Surface/Facility}{description taken from use directions} Disinfectant Cleaner
{Two minute} {Three minute} Surface Disinfectant
10 Second {Hard} Surface Sanitizer
Tuberculocidal
Virucidal*
Veterinary/Animal/Pet Care Facility Disinfectant/Cleaner
With {Contains} Fresh {or appropriate descriptive term} Scent
With {Contains} Rust Inhibitor, Biodegradable Detergent

XL

Extra Large



{These Wipes}{These towelettes}-are disposable, single-use towelette wipes pre-saturated with {Opti-Cide® 3}{Opti-Cide® 1}{Opti-Cide® 2}{disinfectant} solution. This product is intended for use on pre-cleaned, hard, non-porous inanimate surfaces in areas where the disinfection of surfaces is required.

[Use Sites]

When used as directed {these towelettes}{these wipes} clean and disinfect surfaces found in animal transport vehicles, animal/pet care facilities, animal/pet housing facilities, animal labs, athletic clubs, automobile interiors, autopsy rooms, barber shops, bathrooms, blood centers, buses, cadaver work [processing] areas, cardiac care labs, cardiac catheterization labs, cardiology units, central sterile supply, central supply areas, child care facilities (day care, infant care, schools), clean rooms, clinical areas, daycare centers, dental facilities, dialysis units, drug preparation facilities, EMS units, endoscopic rooms, equine facilities, esthetician facilities, extended care facilities, field hospitals, food processing facilities (non-food contact surfaces), funeral homes, GI laboratories, gyms, hair salons, health clubs, hospitals, healthcare facilities, hotels, human transport vehicles, infant care units, institutional facilities, intensive care units, isolation rooms [units], laboratories, large animal care facilities, lasik centers, locker rooms, long-term care facilities, medical facilities (ambulances/EMS/paramedic units, blood banks [centers], clean rooms, dental offices, drug preparation rooms, emergency rooms, infant/child care units, isolation units [rooms] [areas], morgues, neonatal intensive care units, nursing homes, operating rooms, patient care areas, plasma

pheresis centers, surgical centers), medical offices, morgues, nail care facilities, nail salons, neonatal units, newborn nurseries, offices, ophthalmic centers, paramedic squads, pathology facilities, pheresis equipment and centers, podiatry offices, police vehicles, prisoner holding areas [lockups], prisons, radiology centers, research laboratories, respiratory care units, salons (beauty, manicure/pedicure, tanning, tattoo), schools, skin care facilities, small animal/pet care facilities, spas, surgical centers and rooms, trailers, train cars, transport equipment, veterinary facilities, veterinary hospitals, workout rooms, zoologic centers, zoos and areas/facilities concerned with the hazards of cross-contamination from infectious microorganisms.

{Product Name} {This product} may be used on ambulance equipment and [patient care] surfaces, anesthesia equipment surfaces, animal cages (aviary, canine, feline, etc.), animal examination tables, animal habitats, athletic/training facility surfaces, baby/infant care surfaces, backboards, bassinets, bathing units, bed rails, beds, blood pressure devices, breathing masks, cabinets, cages, canine care surfaces, changing tables, commodes, computer keyboards [surfaces], counters, CPR training devices, CT equipment/surfaces, curing lights, dental equipment surfaces/devices, dialysis machine surfaces, diving equipment and air packs, doorknobs, EMS equipment/work surfaces, endoscopic devices, equine care surfaces, equipment surfaces, ER surfaces, examination tables, eye glasses, eye protection devices, feline care surfaces, finished surfaces, firefighter turnout gear, foot spa surfaces, funeral home surfaces, goggles, gonial lenses, hard cervical collars/braces, helmets, hospitality and hotel surfaces, incubators, infant care equipment (bassinets, bed railings, cribs, infant incubator-surfaces, tables, warmers (exterior surface), instrument stands, Isolettes®, kennel cages, kennels, keyboards, kidney machines, laboratory equipment/surfaces, laminated surfaces, large animal care surfaces, light lens covers, litter boxes, loupes, mats, manicure/pedicure tables/chairs, mannequins, mayo stands, medical equipment surfaces/devices, medication infusion surfaces microkeratome surfaces, microscopes, monitor knobs, monitors, morgue tables, MRI equipment surfaces, neonatal/nursery surfaces, non-critical devices, nursing station surfaces, OB [obstetrical equipment] surfaces, occupational therapy devices, office fixtures, OR lights, OR surfaces, OR tables, ophthalmic equipment surfaces/devices, optical wear (excluding contact lenses) oxygen hoods, oxygen tents, painted surfaces, patient bed surfaces, patient care devices, patient care equipment surfaces, patient examination tables, patient stretchers, patient transport surfaces, pet care surfaces, pharmacy surfaces, physical therapy equipment (such as bars, chairs, empty whirlpool tanks, etc.), play-care equipment, play mats, pulmonary function equipment, pumps, radiology equipment surfaces, rails, refrigerators (exterior surface), reptile care surfaces, respirators, respiratory care equipment surfaces, respiratory therapy equipment, shampoo bowls, ship [river, ocean, sea vessel] surfaces, showers [floors/walls], sink faucets, skin care equipment/surfaces, sinks, small animal care surfaces, spirometers, stalls, stair chairs, stretchers, surgical equipment surfaces, surgical microscopes, tables, tanks, tanning bed surfaces, tattooing equipment surfaces/devices, telephones, toilets (rims, seats and exterior surfaces), toys, transport van surfaces, transportation equipment surfaces, turn-out gear, ventilators, walls, warmers (exterior surface), wet/dry suits, wheel chairs, whirlpool surfaces, work stations, wrestling mats, X-ray equipment/surfaces and devices/surfaces potentially contaminated with disease-causing microorganisms [and use sites made of glass, metal, Plexiglas®, plastics (i.e., polycarbonate, polypropylene, polyvinylchloride and polystyrene), clear plastic, baked-on painted surfaces, stainless steel, brass, chrome, copper, acrylic, {and non-porous} vinyl}, powder painted coated surfaces, baked painted surfaces, Formica®, glazed tile, leather, laminated surfaces and {other similar surfaces}.

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A Virus*. This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against Avian Influenza A Virus* ATCC VR-2072 and Influenza Virus* Strain A2/Hong Kong as is expected to inactivate all influenza A viruses* including Pandemic 2009 H1N1 Influenza virus*.

This product has demonstrated effectiveness against Influenza A Virus* and is expected to inactivate all influenza A Viruses* including Pandemic 2009 H1N1 Influenza virus*.

This product has demonstrated effectiveness against Avian Influenza Virus *ATCC VR-2072 and Influenza Virus* Strain A2/Hong Kong and is expected to inactivate all influenza A viruses* including Pandemic 2009 H1N1 {formerly called "swine flu"}.*

[End of Marketing Copy]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not use this product as a baby or skin wipe, or on contact lenses!

This product sanitizes pre-cleaned non-food contact hard surfaces against the following microorganisms at room temperature with a 10- second contact when used as directed:

- *Staphylococcus aureus* [ATCC 6538]
- *Enterobacter aerogenes* [ATCC 13048]

This product disinfects {effectively kills} the following microorganisms at room temperature) with a 2-minute contact time when used as directed:

- *Acinetobacter baumannii* [ATCC 19606]
- Avian Influenza A (H3N2) Reassortant Virus* [ATCC VR-2072]
- *Escherichia coli*-with extended beta-lactamase resistance (ESBL) {E. coli} [ATCC [BAA-196]
- Hepatitis B Virus* {HBV}
- Hepatitis C Virus* {HCV}
- Herpes Simplex II Virus* {HSV 2} G Strain
- Human Immunodeficiency Virus* {HIV-1} {associated with AIDS}
- Influenza A Virus* {formerly called "swine flu"} H1N1
- Influenza Virus* Strain A2/Hong Kong
- *Klebsiella pneumoniae*- Carbapenem-resistant [ATCC BAA-1705]
- *Listeria monocytogenes* [ATCC 19117]
- *Mycobacterium bovis*, BCG {tuberculosis} {TB}
- *Pseudomonas aeruginosa* [ATCC 15442]
- Rotavirus* Strain WA
- *Salmonella enterica* [ATCC 10708]
- *Serratia marcescens* [ATCC 14756]
- *Staphylococcus aureus* [ATCC 6538]
- Methicillin-Resistant *Staphylococcus aureus* {MRSA} [ATCC 33591]
- *Trichophyton mentagrophytes* {ringworm} [ATCC 9533]
- Vancomycin – Resistant *Enterococcus faecium* {VRE}[ATCC 51299]

For Veterinary / Pet Care Use: In addition to the other microorganisms listed on this label this product kills the following microorganisms at room temperature with a 3-minute contact time or as noted when used as directed:

- *Bordetella bronchiseptica* {kennel cough} [ATCC 10580]
- Bovine Viral Diarrhea Virus* {BVDV – Surrogate Hepatitis C Virus}
- Duck Hepatitis B Virus* {DHBV – Surrogate Hepatitis B Virus}
- Canine Distemper Virus* [ATCC VR-128]
- Canine Para-Influenza Virus* [ATCC VR-666]
- *Chlamydia psittaci* {parrot fever}
- Feline Leukemia Virus*
- Infectious Bovine Rhinotracheitis Virus* [ATCC VR-188]
- Murine Norovirus* {Strain MNV-G}
- Poliovirus* I [ATCC VR-58]
- Rhinovirus* [ATCC VR-286]
- *Streptococcus equi* [ATCC 33398]

5 minute contact time:

Canine Parvovirus*

[For canister dispensing:]**Dispensing Directions:**

To start feed, remove cover and discard seal. From the center of the wipe roll, pull up a wipe corner, twist it into a point and thread it through the hole located on the container cover. Pull through about one inch. Replace cover. Pull out first wipe and tear off at an angle. Remaining wipes feed automatically, ready for the next use. When not in use, keep center cap closed to prevent evaporation.

[For flat pack dispensing:]**Dispensing Directions:**

Pull back re-sealable label located on top of pack top about 3/4 of the way. Do not completely remove the label from pack. Remove wipe. Reseal with label to prevent evaporation of solution. To prevent evaporation keep pack sealed when not in use.

[For individual pack dispensing:]**Dispensing Directions:**

Open packet, remove and use.

Cleaning and Sanitizing/Disinfection of Surfaces:

Use a fresh {wipe} {towelette} to pre-clean surfaces of all gross filth and heavy soil. Repeat as necessary until surfaces are visibly clean. To effectively sanitize or disinfect the pre-cleaned surfaces, use a fresh {new} {wipe} {towelette} or turn the wipe over to the clean side to thoroughly wet the surfaces and allow surfaces to remain wet for the appropriate time indicated for the purpose intended.

Additional Special Animal/Veterinary/Pet Care Cleaning Sanitizing/Disinfection of Surface Instructions:

First, remove animal from immediate area; then remove all visible debris, such as animal excrement, and bedding materials, such as blankets, litter, wood chips, hay or straw, and drinking and feeding utensils.

For disinfection of Avian Influenza A, use this product only for surfaces that are not conducive to treatment by immersion or excess liquid (e.g., cages, equipment tables, lab benches, faucet handles, door knobs and similar "high touch" surfaces). Food and drink dispensing and preparation surfaces must be rinsed with potable water prior to use.

HBV, HCV and HIV-1 Precautions: This product effectively inactivates HBV, HCV and HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects can be associated with the potential for transmission of HBV, HCV and/or the human immunodeficiency virus Type 1 {HIV-1} associated with AIDS. **Special instructions for cleaning and decontamination against HBV, HCV and HIV-1 of surfaces/objects soiled with blood/body fluids:** **Personal Protection:** Wear appropriate barrier protection including gloves, gowns, masks and eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces/objects before disinfection. **Contact Time:** Allow the surface to remain wet for 2 minutes prior to wiping. **Infectious Materials Disposal:** Cleaning materials used that may contain blood/body fluids should be autoclaved and/or disposed of in accordance with local regulations for infectious materials disposal.

This product is not to be used as a terminal sterilant or high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter sterile areas of the body. This product may be used to pre-clean or decontaminate critical and semi-critical medical devices prior to sterilization or high-level disinfection.

Storage and Disposal

Do not contaminate food or feed by storage or disposal.

Storage: Store in a cool, well-ventilated area. **Product and Container Disposal:** Dispose of wipe in trash after use. Do not flush. Tightly close lid between uses to retain moisture. **Non-refillable container.** Do not reuse or refill this empty container. Offer empty container for recycling. If recycling is not available, discard container in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if inhaled or absorbed through skin. Causes moderate eye irritation. Avoid breathing vapors and contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

First Aid

If Inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
If on Skin or Clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes.
If in Eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
<p>Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-255-3924 for emergency medical treatment information.</p>	

{The First Aid statements' grid format will be used if market label space permits; otherwise a paragraph format will be used.}

Physical or Chemical Hazards

Do not use or store near heat or open flame.

For product or technical information contact {appropriate contact information}.

Manufactured in the U.S.A. for:

{Appropriate company information}

Product Order No: _____

{ } Denotes alternate language

[] Denotes language that does not appear on the market label